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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,177	12/01/2003	Wilfried Matthis	60133 (70301)	2568
7590 10/19/2005			EXAMINER	
Edwards & Angell LLP P O Box 55874 Boston, MA 02205			REIMERS, ANNETTE R	
			ART UNIT	PAPER NUMBER
			3733	
DATE MAILED: 10/19/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/726,177

Applicant(s)

MATTHIS ET AL.

Examiner

Annette R. Reimers

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/01/03, 06/23/04</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Claim Objections***

There exists an inconsistency in the language of claim 17. In the preamble of claim 17, line 1, applicant recites "Pressure element" with the polyaxial bone screw being only functionally recited, i.e. "for use in a polyaxial bone screw ...", thus indicating that the claim is directed to the subcombination, "Pressure element". However, in claim 17, line 2, applicant positively recites the polyaxial bone screw as part of the invention, i.e. "the polyaxial bone screw comprising", thus indicating that the combination, pressure element and polyaxial bone screw, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes, claims 17-20 will be considered as being drawn to the combination, pressure element and polyaxial bone screw.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Haider (U.S. Patent Number 5,782,833).

Haider discloses an implant comprising a shaft, 14, a holding element, 20, connected with the shaft, wherein the holding element comprises a recess with a U-shaped cross section for receiving a rod, the recess forming two free legs having at one end thereof an inner thread, a closure element, 48, for fixation of the rod inserted into the U-shaped recess, the closure element having an outer thread cooperating with the inner thread of the legs and an abutment cooperating with the closure element to limit a tilting of the closure element about the rod at the time of final tightening of the closure element in the holding element (see figure 4). The closure element comprises a lower side facing the rod and the abutment is a support surface for a section of the lower side of the closure element (see figure 4). The U-shaped recess of the closure element has a bottom and the rod has a diameter, wherein a distance between the bottom of the U-shaped recess to the support surface is smaller than the diameter of the rod (see figures 2 and 4). The abutment is an inward projecting surface on the inside of the free legs of the holding element (see figure 4).

The shaft and the holding element are connected monoaxially. Furthermore, the shaft and the holding element are capable of being formed in one piece. The shaft has a head at one end that is polyaxially connected to the holding element, wherein the implant further comprises a pressure element, 34, having an end facing the closure element for acting upon the head to fix an angular position of the shaft relative to the holding element, and wherein the abutment is provided at the end of the pressure element (see figures 2 and 4). The pressure element comprises a second U-shaped recess with a second bottom corresponding to the recess of the holding element, the

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second U-shaped recess forming third and fourth free legs having a free end in a plane and wherein the abutment is formed by the free end (see figure 5). Regarding the method claims, 13-16, the method of fixing a rod relative to a bone can be inherently performed by the device of Haider.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haider (U.S. Patent Number 5,782,833).

Haider discloses the claimed invention except for the distance being smaller than the diameter by an amount from about 1 percent to about 7.5 percent of the diameter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Haider the distance being smaller than the diameter by an amount from about 1 percent to about 7.5 percent of the diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

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**Conclusion**


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**EDUARDO O. ROBERT**  
**PRIMARY EXAMINER**